JUDGE PRESKA

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

----------X

LORETTA WILLIAMS,

Plaintiff,

-against-

JOHNSON & JOHNSON, JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, L.L.C. f/k/a R.W. JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE, and ORTHO-MCNEIL PHARMACEUTICAL, INC.,

Defendants.

----------X

DOCKET NO.
07 CIV 8067

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff LORETTA WILLIAMS (alternatively referred to as "Plaintiff"), by and through her attorneys PARKER WAICHMAN ALONSO, LLP, hereby sues the defendants JOHNSON & JOHNSON, JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, L.L.C. f/k/a R.W. JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE, and ORTHO-MCNEIL PHARMACEUTICAL, INC. (alternatively referred to as "Defendants"), and alleges as follows:

NATURE OF THE ACTION

1. This is an action for damages suffered by Plaintiff as a direct and proximate result of the Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of the combination transdermal birth control patch known as ORTHO EVRA® (hereinafter referred to as "ORTHO EVRA" or "the subject product").

2. At all times material hereto, ORTHO EVRA was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by the Defendants herein.

PARTIES, JURISDICTION AND VENUE

3. This Court has jurisdiction pursuant to 28 United States Code Section 1332, in that Plaintiff is a citizen of a State which is different from the States where Defendants are incorporated and have their principal places of business.

4. The amount in controversy exceeds SEVENTY-FIVE THOUSAND DOLLARS ($75,000.00), exclusive of interest and costs.

5. Venue in this district is appropriate under 28 U.S.C. § 1391 because a substantial part of the events giving rise to this claim occurred in the district as Plaintiff was prescribed, purchased and used Ortho Evra in this judicial district, and because Plaintiff has at all times relevant resided in this judicial district. Further, venue is proper in this judicial district because the Defendants are doing business in this judicial district.

6. Plaintiff is a natural person and a resident of the State of New York.

7. The Defendant, JOHNSON & JOHNSON, is a New Jersey corporation which has its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

8. At all times material hereto, the Defendant, JOHNSON & JOHNSON, was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling ORTHO EVRA.

9. Upon information and belief, at all relevant times, the Defendant, JOHNSON & JOHNSON was present and doing business in the State of New York and in the Southern District of New York in particular.

10. At all relevant times, the Defendant, JOHNSON & JOHNSON transacted, solicited, and conducted business in the State of New York and derived substantial revenue from such business.

11. At all relevant times, the Defendant, JOHNSON & JOHNSON expected or should have expected that its acts would have consequences within the United States of America, and the Southern District of New York in particular.

12. The Defendant, JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, L.L.C., f/k/a R.W. JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE, (hereinafter referred to as "JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, L.L.C.") is a limited liability company organized under the laws of New Jersey, which has its principal place of business at 920 Route 202 South, P.O. Box 300, Mail Stop 2628, Raritan, New Jersey 08869.

13. At all times material hereto, the Defendant, JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, L.L.C., was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling ORTHO EVRA.

14. The Defendant, JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, L.L.C., is part of the Defendant JOHNSON & JOHNSON's "Family of Companies".

15. Upon information and belief, the Defendant, JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, L.L.C., was formed by a 2001 merger of The Janssen Research Foundation and the R.W. Johnson Pharmaceutical Research Institute.

16. Upon information and belief, at all relevant times, the Defendant, JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, L.L.C. was present and doing business in the State of New York and in the Southern District of New York in particular.

17. At all relevant times, the Defendant, JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, L.L.C. transacted, solicited, and conducted business in the State of New York and derived substantial revenue from such business.

18. At all relevant times, the Defendant, JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, L.L.C. expected or should have expected that its acts would have consequences within the United States of America, and the Southern District of New York in particular.

19. The Defendant, ORTHO-MCNEIL PHARMACEUTICAL, INC., is a Delaware corporation which has its principal place of business at 1000 Route 202 South, P.O. Box 300, Raritan, New Jersey 08869.

20. At all times material hereto, the Defendant, ORTHO-MCNEIL PHARMACEUTICAL, INC., was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling ORTHO EVRA.

21. The Defendant ORTHO-MCNEIL PHARMACEUTICAL, INC. is a wholly owned subsidiary of the Defendant, JOHNSON & JOHNSON.

22. Upon information and belief, at all relevant times, the Defendant, ORTHO-MCNEIL PHARMACEUTICAL, INC. was present and doing business in the State of New York and in the Southern District of New York in particular.

23. At all relevant times, the Defendant, ORTHO-MCNEIL PHARMACEUTICAL, INC. transacted, solicited, and conducted business in the State of New York and derived substantial revenue from such business.

24. At all relevant times, the Defendant, ORTHO-MCNEIL PHARMACEUTICAL, INC. expected or should have expected that its acts would have consequences within the United States of America, and the Southern District of New York in particular.

FACTUAL ALLEGATIONS

25. ORTHO EVRA is a transdermal contraceptive patch designed to prevent pregnancy.

26. The Defendant, ORTHO-MCNEIL PHARMACEUTICAL, INC., describes itself as a "pioneer and leader in contraception and women's health care, offering the broadest range of prescription birth control options, including the first transdermal contraceptive patch, ten birth control pills, and diaphragms."

27. ORTHO EVRA is the first and only transdermal contraceptive patch on the market in the United States.

28. At or about the time of introducing the subject product to the market, the Defendant, ORTHO-MCNEIL PHARMACEUTICAL, INC.'s patent for its best-selling oral contraceptive, Ortho Tri-Cyclen® (hereinafter referred to as "Ortho Tri-Cyclen"), was about to expire.

29. Thus, it was a priority for the Defendant, ORTHO-MCNEIL PHARMACEUTICAL, INC., to obtain FDA approval of ORTHO EVRA so that it could offset the lost income previously realized from Ortho Tri-Cyclen.

30. The Defendants, by and through their agent(s), servant(s) and/or employee(s), filed a New Drug Application ("NDA") for ORTHO EVRA with the FDA on or about December 21, 2000, denoted as NDA 21-180.

31. The NDA states that the intended use of ORTHO EVRA is for the prevention of pregnancy.

32. The subject product's NDA did not include adequate safety data.

33. Notwithstanding the Defendants' assertion in the NDA that ORTHO EVRA was safe for use in the prevention of pregnancy, the Defendants knew or should have known that the subject product was unsafe, defective, unreasonably dangerous, and not fit for its intended purposes.

34. The risk of developing and/or dying from a blood clot is three times as high among women who use ORTHO EVRA compared to women who use traditional oral contraceptive pills.

35. At all times material hereto, and prior to the FDA's approval of the subject product, the Defendants knew or should have known that the risk of developing and/or dying from a blood clot is three times as high among women who use ORTHO EVRA compared to women who use traditional oral contraceptive pills.

36. Prior to the FDA's approval of the NDA for ORTHO EVRA, the only studies specifically examining ORTHO EVRA's effect on humans were Phase III clinical trials funded and conducted by the Defendants.

37. In the aforesaid clinical trials, the subject product caused or contributed to cases of pulmonary embolism and other venous thrombotic injuries.

38. The incidence of embolisms and thrombotic injuries in the aforesaid clinical trials was approximately six times greater than the incidence of such events in a widely used class of oral contraceptives using the hormone levonorgestrel.

39. In recognition of the above-referenced risks, the FDA Medical Officer's Review expressed serious safety concerns regarding ORTHO EVRA when he stated:

> Post-marketing surveillance for DVT (Deep Venous Thrombosis) and PE (Pulmonary Embolism) events will be important, as there are potential serious adverse risks (with two cases of pulmonary emboli in the clinical trials) with this new delivery system for contraception…

ORTHO EVRA, New Drug Application 21-180 Medical Officer's Review (Nov. 20, 2001).

40. The same FDA Medical Officer's Review further stated that:

> "[t]he reviewer's primary concern…is the possible increased risk of VTE and or PE associated with the transdermal delivery of norelgestromin (17deacetyl-norgestimate) for combination hormonal contraception" and wondered if "the transdermal delivery system and the relatively steady-state serum hormone concentrations for 17d- norgestimate and ethinyl estradiol [was] a factor in the two cases of pulmonary emboli seen in the three pivitol studies."

41. Notwithstanding the above, on or about November 20, 2001, the FDA initially approved ORTHO EVRA for use as a contraceptive to prevent pregnancy.

42. The Defendants aggressively marketed ORTHO EVRA shortly following its approval by the FDA.

43. At all times material hereto, the Defendants failed to properly disclose safety hazards associated with ORTHO EVRA.

44. The package insert accompanying ORTHO EVRA formerly stated that "the contraceptive patch is expected to be associated with similar risks" to that of other hormonal contraceptives, including birth control pills, injectables, implants and the vaginal ring.

45. In the same package insert, however, the Defendants stated that the safety information they provide to consumers is "derived primarily from studies of birth control pills."

46. The package insert for the subject product further stated that, while the subject product and other combination hormonal contraceptives contain both an estrogen and a progestin, "[t]here is no epidemiological data available to determine whether safety and efficacy with the transdermal route of administration would be different than the oral route."

47. The package insert further stated:

a. "[i]t is unknown if the risk of venous thromboembolism with ORTHO EVRA use is different than with use of combination oral contraceptives"; and

b. "[i]t is unknown whether ORTHO EVRA is distinct from other combination hormonal contraceptives with regard to the occurrence of venous and arterial thrombosis."

48. The package insert accompanying the subject product is misleading.

49. The package insert accompanying the subject product is in direct conflict with data collected in the Defendants' clinical studies in that the package insert suggested that the risks associated with the subject product are equivalent to that of oral contraceptives.

50. In the seventeen month period from April 2002 through September 2003, the FDA logged 9,116 reports of adverse reactions to ORTHO EVRA.

51. By way of comparison, the leading oral contraceptive, Ortho Tri-Cyclen, which has six times as many users as ORTHO EVRA, only generated 1,237 adverse event reports to the FDA during the six year period from November 1997 through September 2003.

52. From approximately May 1, 2002 through April 30, 2003, there were forty-four adverse events of injury or death associated with the subject product. These incidents related to blood-clots and related brain injuries, deep vein thromboses, pulmonary embolisms, strokes, and heart attacks.

53. From approximately May 1, 2002 through April 30, 2003, there were only seventeen adverse events reported to the FDA related to Ortho Tri-Cyclen for injuries or deaths from blood-clots and related brain injuries, deep vein thromboses, pulmonary embolisms, strokes, and/or heart attacks.

54. Notwithstanding the well documented safety hazards associated with the subject product, the Defendants have never conducted any meaningful post-market surveillance as suggested in the above-referenced FDA Medical Officer's Review.

55. At all times material hereto, the Defendants, by and through their agents, servants and/or employees, failed to adequately warn physicians and consumers, including Plaintiff herein, that the risk of developing blood clots, pulmonary emboli, strokes, heart attacks and/or deep vein thrombosis from ORTHO EVRA is significantly higher than the risk of developing blood clots, pulmonary emboli, strokes, heart attacks and/or deep vein thrombosis while using oral contraceptives.

56. At all times material hereto, the Defendants knew or should have known that the risks of ORTHO EVRA included severe and life threatening complications and side effects.

57. At all times material hereto, the Defendants, by and through their agents, servants, and/or employees, negligently, recklessly and/or carelessly marketed, distributed and/or sold the subject product without adequate instructions or warnings of the subject product's serious side effects and unreasonably dangerous risks.

58. At all times material hereto, the Defendants failed to comply or properly comply with Federal law in connection with the subject product.

59. Plaintiff was initially prescribed and used the subject product from approximately February 2004 through September 2004.

60. Prior to using ORTHO EVRA, Plaintiff was in good health and able to perform all of her usual and customary activities.

61. On or about September 18, 2004, at age 38, Plaintiff presented to the emergency room at Jacobi Medical Center with complaints of left leg pain.

62. Diagnostic testing performed at the aforesaid hospital revealed a large, acute thrombus extending from the left common iliac vein through the left lower extremity just below the popliteal fossa as well as a suspected subsegmental embolus in the right lower lobe and the left lower lobe.

63. Plaintiff was subsequently admitted to the aforesaid hospital where she was placed on anticoagulant therapy.

64. Had the Defendants properly disclosed the risks associated with the subject product, Plaintiff would not have used it.

65. As alleged herein, as a direct and proximate result of the Defendants' negligence and wrongful conduct, and the unreasonably dangerous and defective characteristics of the subject product, Plaintiff suffered severe and permanent physical injuries, including but not

limited to bilateral pulmonary emboli and lower extremity deep venous thrombosis. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

FIRST CAUSE OF ACTION AS AGAINST THE DEFENDANTS (NEGLIGENCE)

66. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs 1 through 65 above, with the same force and effect as if fully set forth herein.

67. At all times material hereto, the Defendants, and each of them individually, had a duty to exercise reasonable care to consumers, including Plaintiff herein, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling, and/or sale of ORTHO EVRA.

68. The Defendants, and each of them individually, breached their duty of reasonable care to Plaintiff in that they negligently designed, developed, manufactured, tested, inspected, packaged, promoted, marketed, distributed, labeled, and/or sold the subject product.

69. Plaintiff's injuries and damages alleged herein were and are the direct and proximate result of the carelessness and negligence of the Defendants as follows:

a. In its design, development, research, manufacture, testing, packaging, promotion, marketing, sale and/or distribution of the subject product;

b. In its failure to warn or instruct, and/or adequately warn or adequately instruct, users of the subject product, including Plaintiff herein, of said product's dangerous and defective characteristics;

c. In its design, development, implementation, administration, supervision and/or monitoring of clinical trials for the subject product;

d. In its promotion of the subject product in an overly aggressive, deceitful and fraudulent manner, despite evidence as to the product's defective and dangerous characteristics due to its propensity to cause serious injury and/or death;

e. In representing that the subject product was safe for its intended use when, in fact, the product was unsafe for its intended use;

f. In failing to perform appropriate pre-market testing of the subject product;

g. In failing to perform appropriate post-market testing of the subject product; and

h. In failing to perform appropriate post-market surveillance of the subject product.

70. The Defendants knew or should have known that consumers such as Plaintiff herein would foreseeably suffer injury as a result of the Defendants' failure to exercise reasonable and ordinary care.

71. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiff suffered severe and permanent physical injuries, including but not limited to bilateral pulmonary emboli and lower extremity deep venous thrombosis. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured.

Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

SECOND CAUSE OF ACTION AS AGAINST THE DEFENDANTS (STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN)

72. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs 1 through 71 above, with the same force and effect as if fully set forth herein.

73. At all times material to this action, the Defendants were responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling ORTHO EVRA.

74. The subject product is defective and unreasonably dangerous to consumers.

75. ORTHO EVRA is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.

76. At all times material to this action, ORTHO EVRA was expected to reach, and did reach, consumers in the State of New York and throughout the United States, including Plaintiff herein, without substantial change in the condition in which it was sold.

77. At all times material to this action, ORTHO EVRA was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, ORTHO EVRA contained unreasonably dangerous design defects and was not reasonably safe as intended to be used,

subjecting Plaintiff to risks that exceeded the benefits of the subject product, including but not limited to the risks of developing blood clots, pulmonary emboli, strokes, heart attacks and/or deep vein thrombosis, which cause serious, crippling injuries and even death in an unacceptably high number of its users;

b. When placed in the stream of commerce, ORTHO EVRA was defective in design and formulation, making the use of ORTHO EVRA more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other contraceptive medications and similar drugs on the market for the prevention of pregnancy;

c. The subject product's design defects existed before it left the control of the Defendants;

d. ORTHO EVRA was insufficiently tested;

e. ORTHO EVRA caused harmful side effects that outweighed any potential utility; and

f. ORTHO EVRA was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff herein, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff, individually and collectively.

78. In addition, at the time the subject product left the control of the Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically

feasible, and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the product's utility.

79. As a direct and proximate result of the subject product's defective design, Plaintiff suffered severe and permanent physical injuries, including but not limited to bilateral pulmonary emboli and lower extremity deep venous thrombosis. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

THIRD CAUSE OF ACTION AS AGAINST THE DEFENDANTS (STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT)

80. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs 1 through 79 above, with the same force and effect as if fully set forth herein.

81. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling ORTHO EVRA.

82. At all times material to this action, ORTHO EVRA was expected to reach, and did reach, consumers in the State of New York and throughout the United States, including Plaintiff herein without substantial change in the condition in which it was sold.

83. At all times material to this action, ORTHO EVRA was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by

Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, ORTHO EVRA contained manufacturing defects which rendered the product unreasonably dangerous;

b. The subject product's manufacturing defects occurred while the product was in the possession and control of the Defendants;

c. The subject product was not made in accordance with the Defendants' specifications or performance standards; and

d. The subject product's manufacturing defects existed before it left the control of the Defendants.

84. As a direct and proximate result of the subject product's manufacturing defects, Plaintiff suffered severe and permanent physical injuries, including but not limited to bilateral pulmonary emboli and lower extremity deep venous thrombosis. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

FOURTH CAUSE OF ACTION AS AGAINST THE DEFENDANT (STRICT PRODUCTS LIABILITY – FAILURE TO WARN)

85. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs 1 through 84 above, with the same force and effect as if fully set forth herein.

86. ORTHO EVRA was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert consumers, including Plaintiff herein, of the dangerous risks and reactions associated with the subject product, including but not limited to its propensity to cause blood clots, pulmonary emboli, strokes, heart attacks, deep vein thrombosis, and other serious injuries and side effects, notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects over other forms of contraception.

87. Plaintiff was prescribed and used the subject product for its intended purpose.

88. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

89. The Defendants, as manufacturers and/or distributors of the subject prescription product, are held to the level of knowledge of an expert in the field.

90. The warnings that were given by the Defendants were not accurate, clear and/or were ambiguous.

91. The warnings that were given by the Defendants failed to properly warn physicians of the increased risks of blood clots, pulmonary emboli, strokes, heart attacks, deep vein thrombosis, and other serious injuries and side effects.

92. The warnings that were given by the Defendants failed to properly warn consumers of the increased risks of blood clots, pulmonary emboli, strokes, heart attacks, deep vein thrombosis, and other serious injuries and side effects.

93. Plaintiff, individually and through her prescribing physician, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

94. The Defendants had a continuing duty to warn Plaintiff of the dangers associated with the subject product.

95. Had Plaintiff received adequate warnings regarding the risks of the subject product, she would not have used it.

96. As a direct and proximate result of the subject product's defective and inappropriate warnings, Plaintiff suffered severe and permanent physical injuries, including but not limited to bilateral pulmonary emboli and lower extremity deep venous thrombosis. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

FIFTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (BREACH OF EXPRESS WARRANTY)

97. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs 1 through 96 above, with the same force and effect as if fully set forth herein.

98. Defendants expressly warranted that ORTHO EVRA was safe and fit for use by consumers and users including Plaintiff for its intended purpose, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested and fit for its intended use.

99. At the time of the making of the express warranties, Defendants knew or should have known of the purpose for which ORTHO EVRA was to be used and warranted the same to be, in all respects, fit, safe, and effective and proper for such purpose.

100. At the time of the making of the express warranties, Defendants knew or should have known that, in fact, said representations and warranties were false, misleading, and untrue in that ORTHO EVRA was not safe and fit for its intended use and, in fact, produces serious injuries to the user.

101. Members of the medical community, including, but not limited to, Plaintiff's physicians, reasonably relied upon the skill and judgment of Defendants, and upon said express warranties, in prescribing, recommending and/or dispensing ORTHO EVRA.

102. Plaintiff relied on the Defendants' express warranties.

103. Defendants breached said express warranties, in that ORTHO EVRA was not safe and fit for its intended use and, in fact, causes debilitating and potentially lethal side effects with greater frequency than safer alternative methods of birth control.

104. As a direct and proximate result of the Defendants' breach of express warranty, Plaintiff suffered severe and permanent physical injuries, including but not limited to bilateral pulmonary emboli and lower extremity deep venous thrombosis. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings

and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

SIXTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (BREACH OF IMPLIED WARRANTIES)

105. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs 1 through 104 above, with the same force and effect as if more fully set forth herein.

106. The Defendants designed, manufactured, marketed, distributed, supplied and sold the subject product for the prevention of pregnancy.

107. At the time that the Defendants manufactured, marketed, distributed, supplied, and/or sold ORTHO EVRA, they knew of the use for which the subject product was intended and impliedly warranted it to be of merchantable quality and safe and fit for such use.

108. Plaintiff, individually and through her prescribing physician, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

109. Plaintiff was prescribed, purchased, and used the subject product for its intended purpose.

110. Due to the Defendants' wrongful conduct as alleged herein, Plaintiff could not have known about the nature of the risks and side effects associated with the subject product until after she used it.

111. Contrary to the implied warranty for the subject product, ORTHO EVRA was not of merchantable quality, and was not safe or fit for its intended uses and purposes, as alleged herein.

112. As a direct and proximate result of the Defendants' breach of implied warranty, Plaintiff suffered severe and permanent physical injuries, including but not limited to bilateral pulmonary emboli and lower extremity deep venous thrombosis. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein

SEVENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (FRAUDULENT MISREPRESENTATION)

113. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs 1 through 112 above, with the same force and effect as if more fully set forth herein.

114. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff, and the public in general, that the subject product had been tested and was found to be safe and/or effective.

115. The representations made by the Defendants were, in fact, false.

116. When said representations were made by the Defendants, they knew those representations to be false and it willfully, wantonly and recklessly disregarded whether the representations were true.

117. These representations were made by the Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the

medical and healthcare community in particular, to recommend, dispense and/or purchase the subject product, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff and the public in general.

118. At the time the aforesaid representations were made by the Defendants and at the time the Plaintiff used the subject product, she was unaware of the falsity of said representations and reasonably believed them to be true.

119. In reliance upon said representations, Plaintiff was induced to and did use the subject product, thereby sustaining severe and permanent personal injuries.

120. The Defendants knew and were aware or should have been aware that the subject product had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

121. The Defendants knew or should have known that the subject product had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

122. The Defendants brought the subject product to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

123. As a result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries, including but not limited to bilateral pulmonary emboli and lower extremity deep venous thrombosis. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise

been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

EIGTHTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (FRAUDULENT CONCEALMENT)

124. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs 1 through 123 above, with the same force and effect as if fully set forth herein.

125. At all times during the course of dealing between the Defendants, Plaintiff and her healthcare providers, the Defendants misrepresented the safety of the subject product for its intended use.

126. The Defendants knew or was reckless in not knowing that its representations were false.

127. In representations to consumers generally and to Plaintiff and her healthcare providers, the Defendants fraudulently concealed and intentionally omitted material information, including but not limited to, the fact that:

a. the subject product was not as safe as other similar products;

b. that the subject product was defective, and that it caused dangerous side effects;

c. that the subject product was manufactured negligently;

d. that the subject product was manufactured defectively;

e. that the subject product was manufactured improperly;

f. that the subject product was designed negligently;

g. that the subject product was designed defectively; and

h. that the subject product was designed improperly.

i. The Defendant was under a duty to disclose to Plaintiff and her healthcare providers the defective nature of the subject product.

128. The Defendants had sole access to material facts concerning the defective nature of the subject product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used the subject product, including the Plaintiff, in particular.

129. The Defendants' concealment and omissions of material facts concerning, inter alia, the safety of the subject product were made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff and her physicians, hospitals and healthcare providers into reliance, continued use of the subject product, and actions thereon, and to cause them to purchase, dispense and/or use the subject product. Defendants knew that all these entities had no way to determine the truth behind the Defendants' concealment and omissions, as set forth herein.

130. Plaintiff, as well as her doctors, healthcare providers, and/or hospitals, reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by the Defendant.

131. As a result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries, including but not limited to bilateral pulmonary emboli and lower extremity deep venous thrombosis. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are

permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

NINTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (NEGLIGENT MISREPRESENTATION)

132. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs 1 through 131 above, with the same force and effect as if fully set forth herein.

133. The Defendants had a duty to represent to the medical and healthcare community and to the Plaintiff, and the public in general that the subject product, had been tested and found to be safe and effective for its intended purpose.

134. The representations made by the Defendants were, in fact, false.

135. The Defendants failed to exercise ordinary care in the representation of the subject product, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce in that the Defendants negligently misrepresented the subject product's high risk of unreasonable, dangerous side effects.

136. The Defendants breached their duty in representing the subject product's serious side effects to the medical and healthcare community, to the Plaintiff, and the public in general.

137. As a result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries, including but not limited to bilateral pulmonary emboli and lower extremity deep venous thrombosis. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise

been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein

TENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (VIOLATION OF GBL §§ 349 and 350)

138. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs 1 through 137 above, with the same force and effect as if fully set forth herein.

139. Defendants engaged in consumer-oriented, commercial conduct by selling and advertising the subject product.

140. Defendants misrepresented and omitted material information regarding the subject product by failing to disclose known risks.

141. Defendants' misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or the knowing concealment, suppression, or omission of materials facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement of the subject product, in violation of New York General Business Law ("GBL") §§ 349 and 350.

142. New York has enacted statutes to protect consumers from deceptive, fraudulent, and unconscionable trade and business practices. Defendants violated these statutes by knowingly and falsely representing that the subject product was fit to be used for the purpose for which it was intended, when Defendants knew it was defective and dangerous, and by other acts alleged herein.

143. Defendants engaged in the deceptive acts and practices alleged herein in order to sell the subject product to the public, including Plaintiff.

144. As a direct and proximate result of Defendants' violations of GBL §§ 349 and 350, Plaintiff has suffered damages, for which she is entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

145. As a direct and proximate result of Defendants' violations of GBL §§ 349 and 350, Plaintiff suffered severe and permanent physical injuries, including but not limited to bilateral pulmonary emboli and lower extremity deep venous thrombosis. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff prays for judgment against each of the Defendants as follows:

a. Awarding actual damages to the Plaintiff incidental to Plaintiff's purchase and use of ORTHO EVRA in an amount to be determined at trial;

b. Awarding treble and/or punitive damages to the Plaintiff;

c. Awarding pre-judgment and post-judgment interest to the Plaintiff;

d. Awarding the costs and the expenses of this litigation to the Plaintiff;

e. Awarding reasonable attorneys' fees and costs to the Plaintiff as provided by law; and

f. Granting all such other relief as the Court deems necessary, just and proper.

Date: Great Neck, New York
September 11, 2007

Respectfully submitted,

PARKER WAICHMAN ALONSO, LLP

By: _____
Jerrold S. Parker (JP-6865)
Andres F. Alonso (AA-8337)
Melanie H. Muhlstock (MM-9309)
111 Great Neck Road, 1st Floor
Great Neck, New York 11021-5402
Telephone: (516) 466-6500

Attorneys for Plaintiff

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

_____
MELANIE H. MUHLSTOCK (MM-9309)